



Express Mail Label No. EV 286855702US

Date of Deposit: 17.Mar.2004

Atty Dkt 2003P04138 US02

**APPLICATION FOR LETTERS PATENT
OF THE UNITED STATES**

NAME OF INVENTOR(S):

David Brumbach
201 Willow Drive
Denver, PA 17517
UNITED STATES OF AMERICA

Lynne Malchiodi
3000 Valley Forge Circle, Apt.247
King of Prussia, PA 19406
UNITED STATES OF AMERICA

TITLE OF INVENTION:

SYSTEM AND METHOD FOR PROCESSING INFORMATION RELATED TO LABORATORY TESTS AND RESULTS

TO WHOM IT MAY CONCERN, THE FOLLOWING IS
A SPECIFICATION OF THE AFORESAID INVENTION



1
SYSTEM AND METHOD FOR PROCESSING
INFORMATION RELATED TO LABORATORY TESTS AND RESULTS

This is a non-provisional application of provisional application serial No.

5 60/455,934 by D. Brumbach et al. filed March 19, 2003.

1. Technical Field

The present invention relates to laboratory testing and more particularly to validating test results throughout the testing life-cycle of a clinical culture in a 10 microbiology testing laboratory.

2. Description of Related Art

Clinical laboratories are tasked with performing tests on clinical cultures to identify organisms which may be causing an infection in a patient. In the normal course 15 of operations, a microbiology laboratory department receives various patient samples collected by physicians. A microbiology technician plates the samples on media and incubate the media. A plated sample is commonly referred to in the art as a "clinical culture". Over the course of time organisms grow on the clinical culture. It is the responsibility of the microbiology technician to identify any organisms (e.g. bacteria, 20 fungus, micro-bacteria, parasite, virus) from the clinical culture which may be causing an infection in the patient and provide any antibiotic information, known to the technician, that may be applicable in treating possible sources of infection.

As is conventional, a laboratory technician analyzes the clinical culture over a period of hours, days or weeks, commonly referred to as the "testing lifecycle" of the 25 clinical culture. Throughout the culture's "testing lifecycle", the technician periodically enters individual test results into a laboratory system as biochemical tests are performed. These individual test results are typically released to the physicians as they occur. Results entered at later stages of the lifecycle should have an expected outcome based on 30 previous results. As one example, if an earlier performed test, such as the Gram Stain test is reported out as many Gram Negative Rods, then in a later performed test, such as an organism ID test, a well-informed technician should expect a Gram Negative Organism as a later test result.

It is incumbent upon the technician to take into consideration the results of earlier tests when entering a later result, so that inconsistent or wrong results are not released to a physician for review.

A drawback of this process is its unpredictability and inconsistency. Specifically,

5 a technician's ability to differentiate between expected and unexpected results depends in large part upon a technician's acquired and remembered knowledge which can vary from technician to technician, his ability to reference charts, manuals and procedures and procedures of supervisory review.

A further drawback of the process is that validation of the culture sample is 10 performed after the culture is finalized (i.e., at the end of the testing lifecycle). This is too late in most instances because any unexpected intermediate results have already been released to a physician for review as they occur. Validation should instead be preferably performed by continuously monitoring and comparing test results as they occur with other culture results throughout the testing lifecycle of the culture, not at the last stage, as 15 is conventional.

A still further drawback is that there is no message capability for informing a technician of what additional steps to take when an unexpected result occurs.

A further drawback is that quantities are not considered during validation, thereby making the validations imprecise.

20 There are no known systems for processing information related to laboratory tests and results which overcome the aforementioned drawbacks.

SUMMARY OF THE INVENTION

The present invention addresses the need for an improved microbiology validation 25 system. During a culture's "testing lifecycle" in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks. The present invention improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review.

30 In accordance with one aspect of the present invention, a method for processing information related to laboratory tests and results comprises: an interface processor that receives user entered data identifying a laboratory test result of a patient and an expected result of the laboratory test. A validation processor compares the laboratory test result with the expected test result and identifies a failure condition in the case where the

laboratory test result fails to match the expected test result. A result processor generates an alert message to the user informing the user of the failure condition.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Referring now to the drawings in which like reference numbers represent corresponding parts throughout, where:

FIG. 1 illustrates one embodiment of a microbiology validation system for processing information related to laboratory tests/results;

10 FIG. 2 is an exemplary display image window illustrating a micro validation user defined template (UDT) for constructing a micro-validation definition;

FIG. 3 is an exemplary listing of those micro-validation parameters included in the top portion of the UDT of FIG. 2; and

FIGS. 4 – 10 are computer display image windows of various user interface screens in accordance with aspects of the invention.

15

DETAILED DESCRIPTION OF THE INVENTION

The system of the invention is suitable for use in pharmacy and radiology information systems and enables a user to define simple or complex result validation processes and messages. The system has particular application to a hospital laboratory 20 setting enabling the efficient and accurate analysis of a culture. The analysis of a culture may include reporting various microbe types which may include a bacteria, a fungi, a parasite and a virus. It is in this context that the present invention is described. A processor as used herein is a device and/or set of machine-readable instructions for performing task. A processor comprises any one or combination of hardware, firmware, 25 and/or software. A processor acts upon information by manipulating, analyzing, modifying, converting, transmitting the information for use by an executable procedure, an information device, and/or routing the information to an output device. A processor may use the capabilities of a controller.

The system of the invention provides a number of specific advantages over prior 30 art systems including performing validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and

alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure and in a related aspect, allows the entry of an override comment directly from a validation failure window. With specific regard to messaging, the invention provides the user with the 5 ability to define user messages and allows a user to customize the system to provide reminders to other personnel. The invention also includes a failure management report which lists those tests which have been overridden by a lab technician. With regard to expected and actual test results, the invention provides a validation failure window that displays both an expected test result value and an actual test result value that caused the 10 validation failure and allows a user to define or construct what constitutes an expected result rather than defining exceptions to the expected result.

The disclosed elements to be described herein may be comprised of hardware portions (e.g., discrete electronic circuitry), software portions (e.g., computer programming), or any combination thereof. The system according to the invention may 15 be implemented on any suitable computer running either UNIX, Windows NT, Windows 2000 or Windows XP. Obviously, as technology changes, other computers and/or operating systems may be preferable in the future. The system as disclosed herein can be implemented by a programmer, using commercially available development tools.

One of skill in the art can appreciate that the display image windows illustrated in 20 the figures for the embodiments of the present invention represent one possible arrangement and that other arrangements may be used which may include several image windows in place of one image window illustrated in the figures, or conversely one image window to represent several image windows, or different image window arrangements.

25 The micro-biology validation system is described in a non-limiting context of testing cultures in a clinical microbiology laboratory.

The present invention may be more fully understood with reference to FIG. 1, which illustrates the microbiology validation system 100 in accordance with one embodiment. The micro-biology validation system 100 includes, for example, an 30 interface processor 2, a validation processor 4, a result processor 6 and a micro-validation definitions database 8. The micro-validation definitions database 8 stores micro-validation definitions which define the expected test results for those laboratory tests required to be validated, to be described further below.

The micro-biology validation system 100, in the exemplary embodiment, is comprised of one or more software modules integrated within an external computer system such as a hospital laboratory information system (LIS).

The invention operates in two-stages, a pre-configuration stage and an operational stage. At the pre-configuration stage, a user makes a determination regarding which tests from among the plurality of tests to be performed on a clinical culture require validation. Validation, as defined herein, involves looking for unexpected test results based on user supplied pre-defined expected results. For those tests identified by the user requiring validation, the user creates one or more micro-validation definitions which define an expected result. Once created, the micro-validation definitions are stored in a micro-validations definition database 8 for later recall during the operational stage for comparison with actual test results to make a determination regarding the validity or invalidity of a test requiring validation. The two stages of the process, pre-configuration and processing are described in greater detail as follows.

At the pre-configuration stage, a user (customer) first decides which tests require validation from among those laboratory tests to be performed on a particular clinical culture. In the illustrative example to follow, reference is made to a blood clinical culture. In the specific case of a blood clinical culture, one test typically performed on the blood culture sample requiring validation is a GRAM test. To validate the GRAM test, the user completes a user defined template (UDT) 200 of Figure 2, including data such as: an expected GRAM test result, a plurality of pre-conditions, and one or more further defined tests and their expected results, where the further defined test's expected results are supplied by a user in consideration of the earlier performed GRAM test and its expected result.

A user defines an expected result for user identified tests requiring validation by completing one or more user defined templates (UDTs), such as the exemplary UDT shown in FIG. 2.

FIG. 2 is an exemplary display image window illustrating one embodiment of a UDT template 200. The UDT 200 template, once completed by the user, is stored as a micro-validation definition of the expected result for a particular test requiring validation. Micro-validation definitions are created for those tests requiring validation, as determined by the user.

As stated above, the creation of a micro-validation definition for a test to be validated requires that the user identify the test to be validated along with its expected

result, supply data including pre-conditions and identify any further tests and their respective expected results in consideration of the test to be validated. With regard to any further tests, a user has the option of requiring or not requiring that the actual test result matches an expected test result. This option is provided by checking or not checking the 5 "Req?" entry box 238, associated with the line entry identifying the further defined test on UDT 200 during pre-configuration.

One example of a pre-condition of UDT 200 is the "Incubation Time" field 230 shown in the top portion 202 of UDT 200. In the instant example, the user has entered a value of "1", representing 1 day for the "Incubation Time" field. The user has 10 determined that a necessary pre-condition for validating the "GRAM" test 208 is an incubation time equal to or greater than one day.

Determining whether the incubation time pre-condition is satisfied is carried out by system 100 as follows. Validation processor 4 is configured to check the current date that the test result is observed with the start date of the culture to determine if the 15 incubation time is at least 1 day. If the incubation time is determined to be less than 1 day, the pre-condition is not satisfied and micro-validation is not performed for the "GRAM" test 208.

Upon completing the UDT 200 for a particular test to be validated, the micro-validation parameters provided by the user to fill out the UDT template 200 are stored in 20 the micro-validation database 8 as a single record. The record is comprised of the various pre-condition parameter values and further defined tests and their associated expected values. The micro-validation record is later recalled at various times during the processing stage to perform test validation.

The exemplary UDT 200 of FIG. 2 is shown to be divided into a top portion 202 and a bottom portion 204. The top portion 202 includes fields such as a test description field, i.e., "Test" 208 identifying a laboratory test to be validated, performing institution "Perf Instn" 210, "result" 212, organization group priority ("Org Grp Prio") 214, activation ("Active") 216, "Culture Test" 218, "Source" 220, validation description ("Validation Desc.") 222, validation failure message ("Validation Fail Msg.") 224, "Validation Severity" 226, override comment required ("Override Cmnt Req?") 228, and "Incubation Time" 230. From among the afore-mentioned fields, the fields that define pre-conditions comprise fields 208, 212, 214, 216, 218, 220 and 230 of Figure 2.

The bottom portion 204 of UDT 200 includes a number of entry lines 232a-h for allowing the user to define further laboratory tests 234 and their associated expected test

results 236 for the purpose of validating or invalidating the test requiring validation (e.g., GRAM test 208).

The "Req?" entry box 238 when checked, requires that a further laboratory test, e.g. ORG ID 234, is to be considered as a confirmatory test when performing validation.

5 In the case where two or more further laboratory tests 234 are utilized as confirmatory tests in the bottom portion 204 of UDT 200, then a failure condition occurs whenever at least one confirmatory tests actual result fails to match its expected result.

Table I of FIG. 3 describes the micro-validation parameters illustrated in the top portion 202 of UDT 200 of FIG. 2. The first column 30 of Table I identifies the various 10 micro-validation parameters 208-238. The second column 32 provides a brief description of the micro-validation parameters 208-238 of the first column. For example, it is shown that for the micro-validation parameter "validation severity" 226, a user has the option of selecting one of three messages to be displayed when an unexpected test result occurs, i.e., "INFO", "WARN", or "FAIL". The choice may be different for the different micro- 15 validation tests to be performed. The third column 34 describes how the micro-validation parameters may be stored in micro-validation database 8 in one embodiment.

For the laboratory tests requiring validation, one or more UDTs 200 per test to be validated are completed in the manner described above during the pre-processing stage. When the user completes a UDT 200 for those tests requiring validation, the pre- 20 configuration stage is considered complete.

The processing stage follows the pre-configuration stage and involves the life-cycle testing of a clinical culture over a period of hours, days or weeks. Processing of a culture starts with a physician determining that a culture needs to be obtained from a patient. A culture is obtained from the patient and delivered to the microbiology 25 laboratory. Upon making a determination that a culture is appropriate for the body site, the laboratory accesses the culture into the laboratory information system (LIS), as is conventional.

Throughout the processing stage a laboratory technician performs tests and records results pertaining to a culture under consideration. To carry out the 30 necessary operations involved in the life-cycle testing of a culture, the technician interfaces with the system of the invention via a user interface, referred to herein as a "work-card" for processing information related to laboratory tests and results.

FIG. 4 is a display image window of one embodiment of a so-called "work-card" 400 which is called up on a work-screen by the technician at the outset of the processing stage.

By way of example, the micro work-card 400 of FIG. 4 is shown to a technician 5 in response to the technician calling up a blood culture for a patient. It is to be appreciated that a work-card of a "blood culture" type (C BLD) 411 represents one of a wide variety of culture types that a technician may elect to call up. Other culture types that may be called up by a technician may include, for example, a wound culture, sputum culture, urine culture and so on.

10 Work-card 400 is the display user interface used by a laboratory bench technician throughout the testing lifecycle of a culture that allows the technician to enter, display, review, accept and reject test results as they occur.

15 Work-card 400 is divided into three regions, a first (upper) region 402 including a title field 411, "C BLD (PRELIM)" and various patient demographics, such as name 413 - "Dillow, Raliegh", gender 415 - "M", age 417 - "42", attending physician 419 - "UNKOWN DOCTOR". The title field 411, e.g., "C BLD (PRELIM)" identifies the work-card 400 as a blood culture type of work-card.

20 The second (middle) region 404 of work-card 400 is labeled "Direct Exam" and represents an area for displaying the tests that can be performed directly on the specimen culture. In the instant example, entry line 412 shows under the title "Test ID", MEDIA and under the title "Rslt", PERFORMED. The MEDIA test is a user defined test that is automatically part of the Blood Culture group test. It is noted that some users do not define this test. Of the users who do define the MEDIA test, most users have the test automatically resulted with a "PERFORMED" status for any number of reasons 25 including auditing, inventory, system and internal reasons. Alternatively, a user can manually enter a result for the MEDIA test. An indication to a lab technician that a blood culture has been inoculated and that life-cycle testing has begun is provided by seeing a result in the "Rslt" field, e.g., PERFORMED, in combination with an entry in the Plated date/time field 418, e.g., "09/26/2003". Also shown in the second region 404 is a 30 "Culture Tech Note" field 421 which is used for non-reportable information that may be shared among laboratory personnel using the work-card 400.

The third (lower) region 406 of work-card 400 is labeled "Culture Workshop" and represents an area of the work-card 400 for displaying the status of non-direct tests performed on the culture specimen. The "CULT RPT" test indicated at entry line 423 is

a standard test performed as part of the blood culture group tests. Entry line 423 is automatically displayed whenever a work-card of the blood culture type is brought up by a lab technician.

It is to be appreciated that the layout of work-card 400 represents one embodiment which is representative of the paper legacy system from which it is derived. Other layouts are within the contemplation of the invention.

FIG. 5a is a display image window of the work-card 400 of FIG. 4 in the normal progression of preparing the blood culture. FIG. 5a illustrates the same data shown in FIG. 4 and additionally includes entry-line 512 in the "Direct Exam" region 404 of the work-card 400 indicating that the technician has performed a gram stain test, i.e., "GRAM", and observed its corresponding test result, i.e., "MANY GRAM NEGATIVE RODS". Entry-line 512 further shows that the result has been entered, i.e., see "ENT" 514 under the heading "Rs1t Sts" into the system 100. ENT status is indicative of a result that has been entered into the system but not yet released to a physician for review.

As is well known to those knowledgeable in the testing arts, preparatory steps for performing a gram stain test include inoculating the culture sample onto an appropriate media, and a microscopic slide and placing the inoculated media in an incubator for overnight incubation. Subsequent to the incubation period, the technician performs the Gram Stain test and enters the test result into the system 100.

The process of entering a test result is now described with reference to FIGS. 1 and 5 and Table II below.

With reference first to FIG. 1, as tests are performed, such as the gram stain test, results are entered into the system 100. Tests are entered via interface processor 2 which is configured to receive input data, including test result data, at different time stages throughout the testing life-cycle of the culture.

Table II illustrates the various types of data which may be received by the interface processor 2 of FIG. 1. The first column is a description of the various data types and the second column is a description of specific examples of those data types as used in the instant example.

30

Table II.

Generalized input	Exemplary input
	GRAM test

a FIRST laboratory test identifier 5 : identifies a laboratory test requiring validation processing,	
An EXPECTED first laboratory test result 7	GNRGRP – i.e., MANY GRAM NEGATIVE RODS
An ACTUAL first laboratory test result 9	GNRGRP- i.e., MANY GRAM NEGATIVE RODS * Note: the actual result 9 matches the expected result 7.
a FURTHER laboratory test identifier 11 : identifying a further laboratory test for validating the first laboratory test	ORG ID
An EXPECTED FURTHER laboratory test result 13	GNRGRP
An ACTUAL FURTHER laboratory test result 15	Staphlococcus Aurues * Note: the actual further test result 15 does not match expected further laboratory test result 13.

Validation processor 4 performs validation processing by comparing an actual laboratory test result 9 (row 3 of Table II) with an expected test result 7 (row 2 of Table II) for the test requiring validation, e.g. Gram test 208 of Figure 2 and for the further performed tests which are performed at a later stage to validate or invalidate the test to be validated, e.g., Gram test 208. In Figure 2 a single further performed test is shown for the purpose of validating the Gram test 208. The further performed test shown is the ORG ID test 234 with its expected result, i.e., GNRGRP 236. A failure condition is identified

5

10

when an actual laboratory test result 9 (row 3 of Table II) fails to match its expected result 7 (row 2 of Table II) for the test to be validated, e.g., the Gram test 208. A failure condition is also identified when a further performed actual test result 15 (row 6 of Table II) fails to match its expected test result 13 (row 5 of Table II). In those cases where a 5 failure condition occurs, the result processor 6 generates an alert message to the user.

An expected result can be expressed in a number of ways. Some common expressions may be recited by indicating, for example, that the culture is "resistant" to a test compound, or "sensitive" to a test compound. The test result can otherwise be simply expressed as having either a "positive" or "negative" test result.

10 It should be appreciated that an expected result can also be expressed as a qualitative description of a quantity, as recited in the instant example (GRNGRP = many gram negative rods) where the term "many" represents the qualitative description of the quantity "gram negative rods". Other qualitative descriptors used by the present invention include, but are not limited to, "few", "resistant", "sensitive", "positive" and 15 "negative").

Some examples of the qualitative descriptors are as follows. If the test to be validated is, for example, an ORG ID test and its test result is "Klebsiella pneumoniae", then a confirmatory test such as Ampicillin (AM) has an expected result of "resistant". If the ORG ID test result is "Staphylococcus aureus", then a Vancomycin (VA) 20 confirmatory test has an expected result of "sensitive". If the ORG ID test result is "Staphylococcus", then a Catalase confirmatory test (CAT) has an expected result of "positive". If the ORG ID test result is "Streptococcus", then a Catalase confirmatory test has an expected result of "negative".

Another example of using a qualitative quantity indicator would be in the case 25 where a Sputum Culture is used as a confirmatory test (see 218 of FIG. 2) having an expected result of "Many" gram negative rods (GNRGRP). With reference again to FIG. 5a, entering a test identifier and its corresponding test result into system 100 of the invention involves the acts of clicking on the "Add Test" icon 516 of work-card 400 of FIG. 5a. In response, the pop-up window 550 of FIG. 5b is displayed to the technician. 30 Area 580 of pop-up window 550 lists the various tests that can be added by the technician for the blood culture example. In the instant example, the technician would highlight the "GRAM" test and click on the "Add" icon 582 causing the pop-up window 550 to disappear and entry-line 512 to appear on work-card 400 of FIG. 5a.

The test result for the GRAM test, as observed by the technician, is then entered into system 100 by pressing the "Enter Result" icon 518 of work-card 400 of FIG. 5a. In response, pop-up window 570 of FIG. 5c is displayed to the technician. Pop-up window 570 includes a quantity menu 590 and a description menu 592 wherein the quantity menu 590 lists a menu of test result quantities, and a description menu 592 lists a menu of test result descriptions. In the instant example, for a "many gram negative rods" result for the GRAM STAIN test, the technician would select "MANY" from the quantity menu 590 and "GNR" from the description menu 592. Upon clicking on the "Add" icon 594, the coded text result "MANY GRAM NEGATIVE RODS" is displayed in the coded text result region 596 of the pop-up window 570 thus providing the technician with a further opportunity to revise the choice made prior to clicking on the "Apply" icon 598. Subsequent to clicking on the "Apply" icon 598, the entered test result appears on line 512 of the work-card 400 of FIG. 5a as 'MANY GRAM NEGATIVE RODS'.

Next, in the normal course of testing a blood culture sample, at a later stage, the technician receives the blood culture sample with organisms grown on it. A number of bio-chemical tests are performed and the results entered into system 100 via work-card 400. In the instant example, the bio-chemical tests performed on the blood culture sample result in a determination of "Many Staph Aurues". The technician enters the test results for the later performed biochemical tests by clicking on the "Add/Edit Org" button 520 of the work-card 400 of figure 5a to enter the organism tests/test results and an organism identification.

FIG. 5d is a pop-up window 580 that is displayed to a technician in response to the technician clicking on the "Add/Edit Org" button 520 of Figure 5a. Individual biochemical tests are entered in area 602. As the results are entered, they appear in the upper right-hand portion 606 of the pop-up window. Organism quantities and identifications are entered in region 604, the results of which appear in the lower right-hand region 608 of the pop-up window.

In the illustrative example, the technician performs two bio-chemical tests, a catalyse test, "CAT" and a tube coagulase test, "TUBE". Both test results are determined by the technician to be positive resulting in an organism identification of "Many Staphlococcus Aurues". The technician clicks on the "Apply" icon 610 to accept the results..

FIG. 6 is a display image window of work-card 400 in response to the technician clicking on the "Apply" icon 610 in FIG. 5d. The display image window includes new

entry line 416 in region 406 which represents information about the bio-chemical tests performed and the organism identification. It is well known to those in the art that an organism identification of "Many Staph Aureus" is not a type of Gram Negative Rod as expected. The expected result is "GNRGRP" 236 (see Figure 2). If the incorrect result is 5 attempted to be released to a physician for review, it would result in a validation failure.

At this point it is instructive to describe the various ways in which a result can be released to a physician for review. In general, three status types exist: "Enter status", "Review Status" and "Release Status". "Enter Status" defines the case where a technician enters a test result into the system 100 but does not make that result available 10 to the floor. "Review Status" defines the case where a supervisor reviews a test result prior to allowing it to be entered to the floor and "Release Status" defines the case where the result is both entered into the system 100 and released to a physician for review. The status conditions described above are implemented in the work-card 400 via four icons.

With reference now to FIG. 6, four icons are shown on the lower left-hand portion 15 of work-card 400, i.e., "Comp/Save" 420, "Rel/Save" 422, "Rel/Fin/Save" 424 and "Comp/Fin/Save" 426. Various options are provided here to accommodate different laboratory policies and levels of technician professionalism for the review of results.

The "Comp/Save" icon 420 is used to save a test result when the test result has 20 been reviewed by either a supervisor or a lab technician with appropriate security credentials. The review may take place on-line or by using work-card 400 printouts. It is assumed that additional tests are performed subsequent to saving the instant result. In other words, the end of the culture's testing lifecycle has not been reached. Subsequent to the review, the test result is released to a physician for review.

The "Rel/Save" icon 422 is applicable to those cases where a lab technician does 25 not possess appropriate credentials and a supervisory review is mandated. It is assumed that additional tests are performed subsequent to saving the instant result. In other words, the end of the culture's testing lifecycle has not been reached.

The "Comp/Fin/Save" icon 424 is applicable at the end of a culture's testing 30 lifecycle identical and includes the features described above for the "Comp/Save" icon. In addition to the afore-mentioned features, the "Comp/Fin/Save" icon 424 saves any updated/unsaved data to the database 8. At this point in time, the culture status changes from "preliminary" to "final" (see "C BLD (PRELIM)" 411 of Figure 4).

The Rel/Fin/Save icon 426 may also be used to finalize the lifecycle testing of the culture, however, in this case the technician needs to perform an additional step.

Specifically, the technician is required to manually perform a REVIEW action (located under the work-card 400 menu option).

In the instant example, the technician attempts to release the laboratory test result, i.e., "Many Staph Aureus" for the organism identification test, i.e., "ORG ID" 234. In 5 this case, the actual test result does not match the expected test result, i.e., "Gram Negative Rod" 236. Therefore, attempting to release the actual laboratory test result results in a validation failure.

While a technician would not, under normal circumstances, attempt to release a failed test, for purposes of illustrating aspects of the invention, it is assumed that the 10 technician releases the laboratory test result, i.e., "Many Staph Aureus", by either pressing the "Comp/Save" icon 420 or the "Rel/Save" icon 422.

FIG. 7a is a display image window of a failure validation screen 700 that is displayed to the technician when attempting to release a failed result. The failure validation screen 700 provides the technician with an opportunity to review the detected 15 failure and decide whether or not to override the failure and release the result to a physician.

Independent of the system of the invention, in accordance with pre-existing security measures incorporated into a laboratory information system, each technician is initially provided with a security access status that allows the technician to perform 20 certain functions within the overall laboratory system. One aspect of this security access status allows a technician to override any validation failure whose validation security level status is determined to be either "Informational" or "Warning". In the case where the validation security level status is "Failure", a technician may override the failure if the technician's security status is "validation". An authorization processor, incorporated 25 as part of the laboratory information system, is used to determine the technician's security status and allow or deny the override. With reference to Fig. 7a, a technician can override a failure by pressing the "Yes" icon 716 when the technician's status is "validation".

The failure validation screen 700 is shown to include a number of columns 30 including a first column entitled "Validation Severity" 702 for describing the validation failure severity of the failed test. In the illustrative example, the validation severity is shown as "FAIL". As stated above, the validation severity level is set during the pre-processing stage via UDT 200. Validation severity can be set as one of "INFO", "WARN" or "FAIL".

The second column of the failure validation screen 700 is entitled "Validated TestID/Result" 704 identifying a test to be validated and its expected result. In the instant example, the "TestID/Result" 704 is the GRAM STAIN test 208 (see Figure 2) and the expected result is many gram negative rods "MANY GNR" 212 (see Figure 2).

5 The third column of the failure validation screen 700 is entitled "Failed TestID/Result" 706 identifying a test performed at a later stage of the testing lifecycle of the culture and its observed (actual) result. In the instant example, the ORG ID test is performed at a later stage as a confirmatory test for the earlier performed ORG ID test. As shown in 706, the actual test result for the ORG ID test is "MANY STAAUR".
10 Recall that when constructing the micro-validation definition of the Gram test 208, the ORG ID test 234 of figure 2 is included as a test to be later performed as a validation or confirmatory test, as shown on entry line 232a of figure 2 along with its expected result, GNRGP 236 of figure 2 also shown in the fifth column 710 of Figure 7a. Upon performing the ORG ID test, its actual or observed result, i.e., "MANY STAUUR" 706 is
15 different from its expected test result GNRGRP 236 thereby invalidating the earlier performed GRAM STAIN test 208.

The fourth column of the failure validation screen 700 is entitled "User Message" 708 providing an indication to the technician that the earlier performed test/result 704 to be validated, in this instance, does not match the actual test/result 706. The message shown includes a user prompt recommending that the technician reconfirm the earlier performed test. The message prompts may also include, for example, prompts directing the technician to perform another predetermined laboratory test, prompts directing the technician to repeat a test, prompts providing a user predetermined message and prompts identifying an actual test result and an expected test result.
25

The fifth column of the failure validation screen 700 is entitled "Expected Result" 710 identifying the later performed test and its associated expected result. In the instant example, an expected result for the later performed "ORG ID" test is "GNRGRP", i.e., gram negative rods.

The sixth column of the failure validation screen 700 is entitled "Requires Comment" 712 and displays an "Y" (yes) or "N" (no) to provide a quick indication to the technician if the validation requires a reason for override or not in order for the validation to be overridden. If the column displays "Y" and the technician presses the YES icon 716 (and there is no reason for override entered, see 714) a message is displayed to the technician to enter a reason for override. This column can potentially

save the technician time, by displaying to the technician those cases where a reason is to be entered prior to a validation override. In the instant example, an "N" (no) is shown at 712, indicating no reason for override is required, so the YES icon 716 can be pressed and the validation is overridden without a reason entered at 714.

5 The seventh column of the failure validation screen 700 is entitled "Reason to Override" 714 and provides a display of any "reason for override" that may have been entered. The technician has an opportunity to provide a brief description for overriding the validation failure. Text can be entered for this override field by pressing the "Enter Reason For Override" icon 720 at the top left portion of the Failure Validation Window 10 of Figure 7a. The "reason for override" is incorporated into a validation review record that is reviewable by a supervisor. The validation review record is defined below in connection with FIG. 10.

15 FIG. 7b is a display image window of a pop-up window 750 shown to the technician in response to the technician pressing the "Enter Reason For Override" icon 720 in FIG. 7a. The pop-up window 750 includes a text entry field 752 for providing an override reason. Upon clicking on the "Add" icon 754, the text is included in the text field of the validation window of FIG. 7a at 714.

20 The technician has the option of pressing the "Yes" icon 716 of figure 7a to accept (override) the validation failure and release the later performed test result to a physician or the "No" icon 718 of figure 7a and not release the test result to a physician. It is noted that overriding a validation failure by pressing the "Yes" icon 716 results in the override being included in a management report, reviewable by a supervisor.

25 FIG. 8 is a display image window of work-card 400 shown to the technician in response to the technician pressing the "No" icon 718 at the failure validation screen of FIG. 7a. When a technician presses the "No" icon 718 and chooses to not accept the test results for a validation failure, the technician has a number of options including re-reading the gram stain again, entering a new result for the gram stain or going back to the original blood culture and starting again. Selecting the "No" icon 718 prevents the test result from being released to a physician for review. It is noted that the entry line 416 of 30 figure 8 (shown scrolled to the right relative to that shown in FIG. 6) includes an ENT entry 433 under the heading "Rs1t Sts". This indicates that the result is saved to the database 8 but not yet released to a physician for review. Entry line 416 further shows the biochemical tests performed on the organism and the associated results 431. In the illustrative example, two biochemical tests performed on the blood culture are shown,

i.e., the CAT test and the TUBE test, both having a positive P result. It should be appreciated that the two biochemical tests, CAT and TUBE, can also be validated, if the user desires, in the manner described above. In other words, a test used to validate an earlier performed test may itself be validated by a later performed test. It is noted, 5 however, that to validate any test, a UDT 200 is required to be filled out during the pre-processing stage.

FIG. 9 is a display image window of work-card 400 shown to the technician in response to the technician pressing the "Yes" icon 716 at the failure validation screen of FIG. 7a. Selecting the "Yes" icon 718 releases the test result to the physician. It is noted 10 that the entry line 416 of figure 8 (shown scrolled to the right relative to the same line shown in figure 6) includes a COMP entry 417 under the heading "Rslt Sts". The COMP entry indicates that the result has been saved to the database and released to a physician for review.

In the instant example, the "ORG ID" test is performed as the last validating or 15 confirmatory test for the blood culture under consideration. Therefore, subsequent to performing the ORG ID test and recording the result, the technician presses the "Rel/Fin/Save" icon 424 to finalize the life-cycle testing of the blood culture.

FIG. 10 is a display image window of a Review Validation Window 1000. The review validation window 1000 is available from a drop down list on the work-card 400 20 of figure 9. In the case where a culture had one or more overridden validations, a supervisor has the ability to review a list of overridden failure validations and has the option to continue with the process of finalizing the culture by pressing the "Yes" icon 1002 or otherwise decide to not finalize the process by pressing the "No" icon 1004.

Although this invention has been described with reference to particular 25 embodiments, it should be appreciated that many variations can be resorted to without departing from the spirit and scope of this invention as set forth in the appended claims. The specification and drawings are accordingly to be regarded in an illustrative manner and are not intended to limit the scope of the appended claims.